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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/623,514	03/29/2001	Jitao Zou	43922	8673

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EXAMINER
BAUM, STUART F

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 05/21/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/623,514	ZOU ET AL.	
	Examiner	Art Unit	
	Stuart F. Baum	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 March 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *5,7 and 22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6,8-21 and 23-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

1. The amendment filed 3/6/2003 has been entered.

Claims 1-31 are pending.

Claims 5, 7, and 22 are withdrawn from consideration for being drawn to a non-elected invention.

Claims 24-31 are newly added.

2. Claims 1-4, 6, 8-21 and 23-31 are examined in the present office action.

3. This application contains claims 5, 7, and 22 drawn to an invention nonelected with traverse in Paper No. 14. A complete reply to the final rejection must include cancelation of nonelected claims (37 CFR 1.144) See MPEP § 821.01.

4. Rejections and objections not set forth below are withdrawn.

5. The text of those sections of Title 35, U.S. Code not included in this office action can be found in a prior office action.

Indefiniteness

6. Claims 1-4, 6, 10-21, and 23-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is maintained for the reasons of record set forth

in the Official action mailed 11/6/2002 and to the extent that this is a new rejection necessitated by Applicant's amendment. Applicant's arguments filed 3/6/2003 have been fully considered but they are not persuasive.

7. In claim 1, it is unclear if "functional part" refers to any functional aspect of SEQ ID NO:1 or if it refers to the diacylglycerol acyltransferase activity function of the polypeptide encoded by SEQ ID NO:1.

8. In claim 1, the metes and bounds of "substantially homologous" cannot be determined since Applicant has not adequately defined this term. All subsequent recitations of "substantially homologous" are also rejected. This rejection is maintained for the reasons of record set forth in the Official action mailed 11/6/2002. Applicant's arguments filed 3/6/2003 have been fully considered but they are not persuasive.

Applicants contend that the specification defines this term and as such renders this term definite.

Applicant's traversal is unpersuasive because it is not clear if a substantially homologous sequence still maintains the activity of SEQ ID NO:1 or 3. As amended, the recitation of "substantially homologous" used in the claims is inconsistent with the definition of "substantially homologous" in the specification. It is unclear whether the "substantially homologous" sequence in the claims has diacylglycerol acyltransferase activity, while the definition given in the specification does not require diacylglycerol acyltransferase activity. Further, it is unclear whether percent identity is referring to sequence identity or functional identity. It is unclear what

is meant by "25% or greater identity, and 40% or greater similarity". Are identity and similarity synonymous? What kind of sequence has both 25% sequence identity and 40% similarity?

9. In claim 17, it is not clear what is encompassed by "genomically-unmodified" since all plants have some degree of genetic modification. This rejection is maintained for the reasons of record set forth in the Official action mailed 11/6/2002. The amended claim still recites "genomically-unmodified".

10. In claim 21, it is unclear whether the scientific names within the parentheses are intended to be claim limitations. It is suggested that only the scientific name be used in the claim for clarification. This rejection is maintained for the reasons of record set forth in the Official action mailed 11/6/2002. Applicant's arguments filed 3/6/2003 have been fully considered but they are not persuasive.

Applicants contend that the information in parentheses is an alternative way of referring to the listed plant and does not constitute a further limitation.

The Examiner contends that it is not clear which name, i.e., the common name or botanical name, supersedes. There are different species of plants that have the same common name but different botanical names.

11. All 112 second rejections are maintained for claim 23 as claim 23 was not included in the clean copy of the amended claims.

12. In claim 1, "corresponding to" should be replaced with --encoding--. All subsequent recitations of "corresponding to" are also rejected.

13. In claim 1, the metes and bounds of "functional part" have not been defined. It is unclear if "functional part" refers to the diacylglycerol acyltransferase activity in the preamble. Applicant needs to explicitly state the "function" which is to be measured. Many proteins bind to other proteins while carrying out a catalytic activity. The binding of a protein to another is facilitated by a "functional part" of the protein even though it is separate from the domains or portions of the protein that make up the 3-dimensional catalytic site. All subsequent recitations of "functional part" are also rejected.

14. In claims 1 and 2, 2nd line, "includes" should be replaced with --comprises--.

In claims 12 and 13, 2nd line, "a" should be replaced with --the--.

In claim 14, 2nd line, delete the first recitation of "oil".

In claim 19, 6th line, insert --or-- in between "SEQ ID NO:1" and "SEQ ID NO:3".

Utility

15. Claims 1-4, 6, 10-21, 23, 25, and 27 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility. This rejection is maintained for the reasons of record set forth in the Official action mailed 11/6/2002. Applicant's arguments filed 3/6/2003 have been fully considered but they are not persuasive.

Applicants contend that the claims have been amended to include that the nucleic acid molecule corresponds to a polypeptide having diacylglycerol acyltransferase activity and that "the part of SEQ ID NO:1 or 3 is a functional part".

The Examiner contends that amended claim 19 is still drawn to "a part of SEQ ID NO:1 or 3 and that simply adding the recitation "a functional part" does not render the utility rejection moot. Applicant has not specified what is the intended function. For limitations drawn to "a functional part of SEQ ID NO:1 or 3" or "substantially homologous to SEQ ID NO:1 or 3", Applicant needs to include "wherein the sequence has diacylglycerol acyltransferase activity" to overcome the utility rejection.

Applicants contend that SEQ ID NO:3 includes the *Arabidopsis* DGAT gene (page 12, last paragraph) and that SEQ ID NO:3 differs from SEQ ID NO:1 in that SEQ ID NO:3 is derived from the *Arabidopsis* genomic DGAT gene wherein SEQ ID NO:1 is derived from *Arabidopsis* DGAT cDNA. Applicants assert that SEQ ID NO:3 encodes a polypeptide having diacylglycerol acyltransferase activity (page 13, 1st paragraph).

The Examiner asserts that Applicants have not demonstrated that the polypeptide encoded by SEQ ID NO:3 has the same activity as the polypeptide encoded by SEQ ID NO:1, especially in light of the fact that the polypeptide encoded by SEQ ID NO:3 is 22 amino acids shorter than the polypeptide encoded by SEQ ID NO:1. Therefore, absent any additional data or examples, the polypeptide encoded by SEQ ID NO:3 lacks an asserted or well established utility.

Scope of Enablement

16. Claims 1-4, 6, 10-21, 23, 25, and 27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to a DGAT cDNA clone of SEQ ID NO:1 from *Arabidopsis* transformed into wild-type *Arabidopsis* to yield plants with an increased oil content (page 24, line 19) an increase seed weight and an oil content that exhibited a decrease in the total saturates and an increase in the monounsaturates (page 24, line 23) does not reasonably provide enablement for claims broadly drawn to an isolated DNA molecule comprising a part of SEQ ID NO:1 or 3, or a sequence that is substantially homologous to SEQ ID NO:1 or 3; a vector comprising one of the former sequences; a transformed plant or transformed plant seed comprising one of the former sequences; a method of producing a transgenic plant and a method of changing the oil content of a seed comprising transforming a plant with said vector comprising an isolated DNA molecule of SEQ ID NO:1 or 3, a part of SEQ ID NO:1 or 3, or a sequence that is substantially homologous to SEQ ID NO:1 and plants and plant seeds exhibiting an altered seed oil content, an altered diacylglycerol content, an altered fatty acyl composition, and an enhanced biomass. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. This rejection is maintained for the reasons of record set forth in the Official action mailed 11/6/2002. Applicant's arguments filed 3/6/2003 have been fully considered but they are not persuasive.

Applicants contend that SEQ ID NO:3 is enabled since one skilled in the art would be able to clone SEQ ID NO:3, a part of SEQ ID NO:3 or a sequence that is substantially homologous to SEQ ID NO:3. Applicants also contend that a functional part of SEQ ID NO:1 or

3 is also enabled because the claims are drawn to a sequence that is a functional part of SEQ ID NO:1 or 3 corresponding to a polypeptide with DGAT activity. Applicants assert that a functional part of SEQ ID NO:1 or 3 would include at least 1560 nucleotides that encode the open reading frame of TAG1.

The Office disagrees with Applicant that just because SEQ ID NO:1 is enabled, one of skill in the art could clone SEQ ID NO:3 and use the cloned sequence as Applicants have used SEQ ID NO:1. Given Applicant's disclosure, it appears that cloning SEQ ID NO:3 and producing a polypeptide identical to SEQ ID NO:1 is not so simple. The polypeptide encoded by Applicant's SEQ ID NO:3 is not identical to the polypeptide encoded by SEQ ID NO:1, even though it is presumably the genomic sequence of SEQ ID NO:1. Given Applicant's claim language, i.e., a functional part, a part, or a substantially homologous sequence, all of which do not encompass the same activity as SEQ ID NO:1 because Applicant has not specified as such in the claims, read on sequences that do not necessarily have the same function as SEQ ID NO:1, and as such, are not enabled. Lastly, it is not clear what is a TAG1 open reading frame? Is that another name for the DGAT cDNA or genomic sequence? Applicant believe that a functional part of SEQ ID NO:1 or 3 would comprise 1560 nucleotides and encode a polypeptide comprising 520 amino acids (page 14, last full paragraph). Specifying in the claims that a functional part of SEQ ID NO:1 or 3 comprises at least 1560 nucleotides of SEQ ID NO:1 or 3 and encodes a polypeptide comprising 520 amino acids and has the same activity as the polypeptide encoded by SEQ ID NO:1 would overcome the enablement rejection for those claims drawn to a functional part of SEQ ID NO:1.

Applicants contend that substantially homologous sequences of SEQ ID NO:1 or 3 are also enabled. Applicants contend that substantially homologous is defined as "DNA sequences from plants encoding proteins with deduced amino acid sequences of 25% or greater, and 40% or greater similarity" and that the before mentioned sequences are enabled (page 15, 1st paragraph). Applicants contend that small changes of nucleotides may function to enhance or reduce the effect of the gene or may act in the same manner as the full length sequence.

The Examiner agrees that small changes in the sequence can potentially enhance or reduce the function of the encoded polypeptide and this is one reason why substantially homologous sequences are not enable. Another reason is based on the "substantially homologous" definition as recited by Applicant (see above), a sequence can comprise only 25% of the original nucleotides and still be encompassed by Applicant's claims even though Applicant has not defined which regions of SEQ ID NO:1 must not be changed or which regions of SEQ ID NO:1 can tolerate alterations and still have the same acitivity as the polypeptide encoded by SEQ ID NO:1. Without this information, it would require undue experimentation by one skilled in the art to identify, isolate and verify sequences possessing the same activity as Applicant's invention.

Deposit Rejection

17. Claims 8 and 9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is maintained for the reasons of record set forth in the Official action

mailed 11/6/2002. Applicant's arguments filed 3/6/2003 have been fully considered but they are not persuasive.

Applicants contend that they have attached a deposit slip from ATCC evidencing deposit of plasmid pDGATcDNA and plasmid pDGATgene, PTA-988 and PTA-989, respectively.

For Applicants to overcome the deposit rejection, Applicants are requested to provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that

(a) during the pendency of the application, access to the invention will be afforded to the Commisioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;

(d) the viability of the biological material at the time of deposit will be tested (see 37 CFR 1.807); and

(e) the deposit will be replaced if it should ever become unviable.

Written Description

18. Claims 1-4, 6, 10-21, and 23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s), at the time at the time the application was filed, had possession of the claimed invention. This is a written description

rejection. This rejection is maintained for the reasons of record set forth in the Official action mailed 11/6/2002. Applicant's arguments filed 3/6/2003 have been fully considered but they are not persuasive.

Applicants contend that the claims are directed to nucleic acids corresponding to a polypeptide having diacylglycerol acyltransferase activity and that the specification discloses amplifying and subcloning a full length cDNA using PCR and that one skilled in the art would be able to determine the correct reading frame without undue experimentation.

The Examiner asserts that without the location of the start and stop codons, there is no evidence of a full length sequence and that each reading frame results in a different polypeptide sequence. It is unclear if Applicant is in possession of all such polypeptides.

Applicants contend that the definition of "substantially homologous" fulfills the written description requirement, (see above for definition and also page 16, 3rd full paragraph of response).

The Examiner asserts that Applicants have not taught which amino acids can be changed and which amino acids are required for proper diacylglycerol acyltransferase activity. Given the broadly recited claims, and the lack of information regarding essential amino acids, it is unclear that Applicant is in possession of a representative number of "substantially homologous" sequences based on the disclosure of SEQ ID NO:1 or 3.

Prior Art (102)

19. Claims 1-4, 6, 10-21, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Cahoon et al (March, 1997, U.S. Patent 5,614,400). This rejection is maintained for the reasons

of record set forth in the Official action mailed 11/6/2002. Applicant's arguments filed 3/6/2003 have been fully considered but they are not persuasive.

Applicants contend that the amended claims recite a polypeptide having diacylglycerol acyltransferase activity, and as such are not anticipated by Cahoon et al.

Applicants traversal is not persuasive. The amended claims recite sequences (i.e., a functional part of SEQ ID NO:1 or 3 and sequences that are substantially homologous to SEQ ID NO:1 or 3) that are not specified as possessing diacylglycerol acyltransferase activity. The amended claims are still anticipated by Cahoon et al.

20. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Newman et al (Sept. 1997, NCBI Database, Accession number AA042298). This rejection is maintained for the reasons of record set forth in the Official action mailed 11/6/2002. Applicant's arguments filed 3/6/2003 have been fully considered but they are not persuasive.

Applicants contend that the amended claims recite a polypeptide having diacylglycerol acyltransferase activity, and as such are not anticipated by Newman et al. The Applicants further contend that when the claims are read in light of the specification, the sequences substantially homologous to SEQ ID NO:1 or 3 are not anticipated by Newman et al.

The Applicant's traversal is not persuasive. It is unclear that the amended claims recite sequences (i.e., a functional part of SEQ ID NO:1 or 3 and sequences that are substantially homologous to SEQ ID NO:1 or 3) that possess diacylglycerol acyltransferase activity, see 112 2nd above. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., sequences of

25% or greater identity, and 40% or greater similarity when compared to SEQ ID NO:1 or 3) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

21. No claims are allowed.

22. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart Baum whose telephone number is (703) 305-6997. The examiner can normally be reached on Monday-Friday 8:30AM – 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 or (703) 305-3014 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist, who may be contacted at 308-0196.

Stuart F. Baum Ph.D.

May 16, 2003

Phuong Bui

PHUONG T. BUI
PRIMARY EXAMINER 5/19/03